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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/875,264 | 06/07/2001 | Smita K. Nair | 1579-579 | 5191 |

7590 02/20/2003

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EXAMINER

WILSON, MICHAEL C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1632

DATE MAILED: 02/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/875,264

Applicant(s)

NAIR ET AL.

Examiner

Michael C. Wilson

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002 and 22 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 21-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

Applicant's election of Group IV in Paper No. 12 (claims 19 and 20) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-18 and 21-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 12.

Claims 19 and 20 are under consideration in the instant office action.

Claim Rejections - 35 USC § 112

1. Claims 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of making cytotoxic T lymphocytes (CTL) comprising: i) introducing RNA encoding an antigen into antigen-presenting cells (APC) *in vitro*, wherein said RNA is isolated from tumor cells or pathogens, thereby producing APC that functionally present said antigen on their surface; ii) contacting the APC produced in step i) with lymphocytes *in vitro*, wherein the lymphocytes comprise cytotoxic T-lymphocytes (CTL), thereby producing CTL that recognize said antigen; and iii) maintaining the CTL produced in step ii) in culture, does not reasonably provide enablement for tumor-specific or pathogen-

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specific RNA, merely contacting a T-cell with an RNA loaded APC that does not functionally present on their surface an antigen encoded by the RNA, or providing any T lymphocyte to obtain a CTL. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for reasons of record.

The specification teaches isolating total RNA from tumor cells, transfecting APC with the RNA to make APC that functionally express antigens encoded by the RNA on their surface. The APC are contacted with CTL to stimulate a CTL response against the antigen encoded by the APC which is measured using a cytotoxicity assay (pg 22, line 8, through pg 23, line 5).

The specification does not teach how to isolate RNA that is specific to pathogens or tumors. The specification does not teach how to separate RNA that is specific to pathogens or tumors from non-specific RNA. One of skill would not know how to separate tumor- or pathogen-specific RNA from non-specific RNA and would require undue experimentation. The specification does not teach how to use an APC that does not express an antigen encoded by the RNA. Expression of an antigen on the surface of the APC is essential to stimulate CTL that recognize an antigen that is encoded by the RNA. The specification does not teach how to contact a T lymphocyte with the RNA-loaded APC to obtain CTL. T-lymphocytes encompass helper and cytotoxic T-cells. Thus, the claim encompasses contacting RNA-loaded APC with helper T-cells to obtain CTL. However, helper T-cells cannot become CTL. It would have required one of skill in the art at the time the invention was made undue experimentation to

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determine how to combine T-cells as broadly claimed with APC expressing an antigen to obtain CTL. Therefore, the T-lymphocytes in the claim must at least comprise CTL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Rouse (1994, J. Virol., Vol. 68, pg 5685-5689).

Rouse taught CTL that recognize viral antigen (pg 5687, col. 2). The method of claim 19 does not bear patentable weight on the CTL produced in claim 20 as compared to the method used to make CTL taught by Rouse. While Rouse does not load APC with RNA as required in claim 19, Rouse transfected the cells with DNA encoding antigen. The result of transfecting APC with DNA encoding an antigen is the same as loading APC with RNA encoding an antigen. Therefore, the CTL produced using APC transfected with DNA encoding an antigen as taught by Rouse is the same as the CTL claimed because it recognizes an antigen on an APC.

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Double Patenting

3. Claims 19 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 09/667319 which are drawn to contacting tumor or pathogen-specific RNA-loaded APC with T-lymphocytes to obtain CTL and determining the CTL response while the instant claims also require contacting tumor or pathogen-specific RNA-loaded APC with T-lymphocytes to obtain CTL to produce CTL.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Carson (US Patent 5,830,877, Nov. 3, 1998) taught contacting RNA loaded APC with T-lymphocytes *in vivo* (e.g. col. 11, line 33, and claim 9).

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.
Michael C. Wilson



**MICHAEL WILSON
PRIMARY EXAMINER**